June 11, 2018

Pollogen Ltd.
% Elissa Burg
Regulatory Consultant
BioVision Ltd
Had Nes 183
Had Nes, 1295000 Israel

Re: K173503
Trade/Device Name: Pollogen Legend System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 8, 2018
Received: April 11, 2018

Dear Elissa Burg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 6 - Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173503

Device Name
Pollogen Legend+™ System

Indications for Use *(Describe)*

The Pollogen Legend+™ System is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO).
It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar RF Energy (Applicators 1-3).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 7 - 510(k) Summary

Pollogen Ltd's Legend$^{+™}$ System

Applicant's name: Pollogen Ltd.
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Date Prepared: June 6, 2018

Name of Device: Pollogen Ltd's Legend$^{+™}$ system

Common or Usual Name: Electrosurgical cutting and coagulation device and accessories

Classification: **Product Code:** GEI
Regulation No: 21 C.F.R. §878.4400
Class: II
Classification Panel: General & Plastic Surgery

Predicate Device: Pollogen Legend$^{+™}$ System (K171359)

Reference Device: INTRAcel Premium Fractional RF Micro Needle (FRM) System (K153727)

Intended Use / Indications for Use

The Modified Legend$^{+™}$ system is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO).
It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar RF Energy (Applicators 1-3).

Modified Device Description

Pollogen Ltd's modified Legend$^{+™}$system delivers bipolar radiofrequency (RF) electrical current to the skin surface for dermatological procedures requiring ablation and resurfacing of the skin. The physician can control the parameters of the device through a user interface.
The system consists of:

- Main Unit (includes the Controller);
- Control Panel (User Interface);
- RF Generator;
- VO (VoluDerm) Treatment Applicator
- Disposable tips; gen12, gen36 & gen36L
- Treatment Applicators 1-3 (TriPollar);
- Foot Switch;
- Patient-Controlled Manual Switch.

The device generates RF energy, which is applied to the skin. The VO (VoluDerm Energy) treatment applicator applies pulses of bipolar RF energy that flows between electrodes to create micro-ablation points on the skin via an array of multi-electrode pins.

The TriPollar treatment Applicators 1-3 apply bipolar RF energy that flows between electrodes on the skin. The three applicators differ in size and configuration and are indicated for treatment of various size facial areas. The operator can adjust treatment parameters, such as the power level and treatment time from the user interface on the Main Unit. The Applicator is applied with a little pressure and a rubbing/massaging technique (linear, circular, etc., depending on the area). The applicator should be moved continuously on the skin. No active cooling of the electrodes or the skin is required.

Technological Characteristics

Pollogen's modified Legend$^{+™}$ system has similar technological characteristics as the Pollogen Legend$^{+™}$ system that was previously cleared under K171359. The primary purpose of this

submission is to add an optional disposable tip, gen36L, to the cleared Legend$^{+™}$ System's VO applicator.

Pollogen Ltd's modified Legend$^{+™}$system consists of a console, Applicators 1-3 (TriPollar) and VO (VoluDerm) hand held applicators, and disposable tips. It is designed to deliver bipolar radiofrequency electrical current to the skin.

Performance Data

Pollogen conducted several performance tests to demonstrate that the modified Legend$^{+™}$ system complies with the following standards and that it functions as intended.

- IEC/EN 60601-1 Edition 3.1 - Medical Electrical Equipment Part 1: General requirements for safety (2005/AMD:2012).
- IEC/EN 60601-2-2 Medical Electrical Equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (2009)
- IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (2007, Ed. 3).
- IEC 60601-2-2 Medical electrical Equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (2006); clauses 36.201 (Emission) & 36.202 (Immunity)
- IEC 62304 Medical device software – Software life cycle processes (2006/AMD2015)
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-7:2008 - Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

Animal Study

An animal study was conducted, 3 pigs underwent treatment for ablation and resurfacing of the skin with the modified Legend$^{+™}$system while using the gen36L tip. There were no procedure related complications or premature deaths in this study, for all follow-up evaluation time points up to two weeks.

The safety and effectiveness of the modified Legend$^{+™}$system was evaluated by macroscopic and histological evaluation of the tissue in the treatment areas. These studies demonstrated that the modified Legend$^{+™}$system can safely perform ablation and resurfacing of the skin for dermatological procedures.

Substantial Equivalence

The following table compares the modified Legend$^{+™}$system to the predicate device with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

	Subject Device: **Modified Pollogen Ltd.** **Legend$^{+™}$system – Applicator VO and Applicators 1-3** **(K173503)**	**Predicate Device:** **Pollogen Ltd.** **Legend+ system – Applicator VO and Applicators 1-3** **(K171359)**
Device Class	Class II	Class II
Classification Panel	General and Plastic Surgery	General and Plastic Surgery
Product Code	GEI	GEI
Regulation Description	Device, electrosurgical, cutting and coagulation device and accessories.	Device, electrosurgical, cutting and coagulation device and accessories.
Regulation Number	21 C.F.R. §878.4400	21 C.F.R. §878.4400
Intended Use and clinical indication	The Modified Pollogen Legend$^{+™}$ system is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO). It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar RF Energy (Applicators 1-3).	The Pollogen Legend$^{+™}$ system is intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO). It is also intended for use in dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar RF Energy (Applicators 1-3).

Device Description	The Modified Pollogen Legend$^{+™}$ system is composed of a console, VO hand held applicator and disposable tips, designed to deliver bipolar radiofrequency electrical current to the skin surface, via an array of multi-electrode pins. It is also composed of 3 treatment applicators, foot switch and Patient-controlled manual switch. User interface allows the selection of treatment parameters: applicator, power and time and displays the current settings. The RF module provides RF energy to applicators at 1 MHz frequency. The treatment applicators transmit Bi-Polar RF energy through multiple electrode configuration which produces homogenous heating of the treatment area.	The Pollogen Legend$^{+™}$ system is composed of a console, VO hand held applicator and disposable tips, designed to deliver bipolar radiofrequency electrical current to the skin surface, via an array of multi-electrode pins. It is also composed of 3 treatment applicators, foot switch and Patient-controlled manual switch. User interface allows the selection of treatment parameters: applicator, power and time and displays the current settings. The RF module provides RF energy to applicators at 1 MHz frequency. The treatment applicators transmit Bi-Polar RF energy through multiple electrode configuration which produces homogenous heating of the treatment area.
Principles of Operation:	The Modified Pollogen Legend$^{+™}$ VO hand piece is designed to deliver radiofrequency energy to the skin in a non-homogeneous fractional manner, via an array of multi-electrode pins. The array delivers bipolar RF energy to the skin, resulting in heating of skin directly below the electrodes, to temperatures leading to ablation and resurfacing of the skin. Applicators 1-3 provide RF energy that heats biological tissue in a controlled fashion for non-ablative therapeutic effects. Non ablative effects are used to trigger collagen remodeling for the treatment of wrinkles and rhytides.	The Pollogen Legend$^{+™}$ VO hand piece is designed to deliver radiofrequency energy to the skin in a non-homogeneous fractional manner, via an array of multi-electrode pins. The array delivers bipolar RF energy to the skin, resulting in heating of skin directly below the electrodes, to temperatures leading to ablation and resurfacing of the skin. Applicators 1-3 provide RF energy that heats biological tissue in a controlled fashion for non-ablative therapeutic effects. Non ablative effects are used to trigger collagen remodeling for the treatment of wrinkles and rhytides.
Energy Source:	RF (Bipolar)	RF (Bipolar)
Frequency:	1 MHz	1 MHz
Maximum Output Power	44 Watts on 300 ohm for VO applicator. 50 Watts on 200 ohm for applicators no. 1 and no.2. 15 Watts on 200 ohm for applicator no. 3.	44 Watts on 300 ohm for VO applicator. 50 Watts on 200 ohm for applicators no. 1 and no.2. 15 Watts on 200 ohm for applicator no. 3.
Electrical Requirements	100-240 Volt, max 2.2A, 50- 60Hz	100-240 Volt, max 2.2A, 50-60Hz
System Weight	~30 Kgs/66.14 lb	~30 Kgs/66.14 lb

Applicator Weight	A1- 0.78 Kg A2- 0.66 Kg A3- 0.6 Kg VO- 0.47 Kg	A1- 0.78 Kg A2- 0.66 Kg A3- 0.6 Kg VO- 0.47 Kg
System Dimensions: h•w•d	110cm x 45cm x 45cm 43.3" x 17.72" x 17.72"	110cm x 45cm x 45cm 43.3" x 17.72" x 17.72"
Number of Applicators	4	4
Applicator Type	VO: Fractional Bi Polar RF A1: Bi Polar RF A2: Bi Polar RF A3: Bi Polar RF	VO: Fractional Bi Polar RF A1: Bi Polar RF A2: Bi Polar RF A3: Bi Polar RF
Comparison of disposable tips	gen 12, gen 36, gen 36L	gen 12, gen 36
Number of electrode pins	gen 12: 6x2 gen 36: 6x6 gen 36L: 6x6	gen 12: 6x2 gen 36: 6x6
The distance between the electrode pins	gen 12: 2.2mm gen 36: 2.2mm gen 36L: 2.2mm	gen 12: 2.2mm gen 36: 2.2mm
Treatment area size	gen 12: 11x2.2mm gen 36: 11x11mm gen 36L: 11x11mm	gen 12: 11x2.2mm gen 36: 11x11mm
Electrode pin's diameter	gen 12: 150 microns gen 36: 150 microns gen 36L: 150 microns	gen 12: 150 microns gen 36: 150 microns
Electrode pin's length	gen 12: ~600 microns gen 36: ~600 microns gen 36L: ~1000 microns	gen 12: ~600 microns gen 36: ~600 microns
RF energy per pin	up to 62mJ/pin	up to 62mJ/pin
Maximum number of pulses	800	800
Modes of Operation (Treatment programs):	VO: Low, Medium, High A1: A1-A; A1-B A2: A2-A; A2-B A3: A3-A; A3-B	VO: Low, Medium, High A1: A1-A; A1-B A2: A2-A; A2-B A3: A3-A; A3-B
Biocompatibility	All parts that are in contact with patient comply with the requirements of ISO 10993-1	All parts that are in contact with patient comply with the requirements of ISO 10993-1
Software	Verified and validated according to the FDA guidance.	Verified and validated according to the FDA guidance.

Pollogen's modified Legend$^{+™}$ system has the same intended use and indications for use and similar technological characteristics and principles of operation as its predicate device. No technological differences exist between the modified Legend$^{+™}$ system and its predicate device, except for the addition of an optional disposable tip gen36L that can be used with the VO applicator.

The minor difference in the length of the electrode pins of the gen36L has been demonstrated via the reference predicate device, INTRAcel Premium (K153727), an RF energy device for electrocoagulation procedures that has the same or longer length pins and therefore, the minor increase in pin length does not raise new or different questions of safety or effectiveness. Furthermore, performance data and a pre-clinical study both demonstrate that the modified Legend$^{+™}$ system is as safe and effective as its predicate device.

Thus, Pollogen's modified Legend$^{+™}$ system is substantially equivalent to its predicate device.